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4. (Once Amended) Crystals according to claim 1, wherein the volume mean spherical equivalent diameter is from 1.5 microns to 4.5 microns.

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6. (Once Amended) A process for preparing crystals according to claim 1, comprising;

a) preparing a crystallization solution comprising insulin, an insulin analog, a derivatized insulin or a derivatized insulin analog, a buffer, a salt and a divalent cation;

b) combining the crystallization solution of step a) with a nucleating seed suspension; and

c) allowing time for the seeded crystallization solution of step b) to generate the crystals.

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20. (Once Amended) A pharmaceutical composition for administration by inhalation by mouth comprising the crystals according to claim 1.

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24. (Once Amended) Use of the crystals according to claim 1 to prepare a medicament for the treatment of diabetes or hyperglycemia by mouth.

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25. (Once Amended) A method of using the crystals according to claim 1 to treat diabetes or hyperglycemia using a device to administer the crystals by inhalation via the mouth to a patient in need of such treatment.

26. (Once Amended) A method of treating diabetes comprising administering the pharmaceutical composition according to claim 20 to a patient in need thereof to regulate blood glucose levels in the patient.

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